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6485/16895

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Giancarlo SANTUS ET AL.

Serial No: N/A

Group Art Unit: N/A

Filed: concurrently herewith  
(Rule 53(b) Continuation of 08/383,707)

Examiner: N/A

For: THERAPEUTIC COMPOSITIONS FOR INTRANASAL  
ADMINISTRATION WHICH INCLUDE KETOROLAC

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INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a  
copy of Form PTO-1449. Copies of previously-disclosed references for the prior art

can be located in the parent applications except for Zia et al. (U.S. Patent No. 6,090,368) which is attached. These documents contain information which the Examiner should consider during examination of the present application.

The present application incorporates a concise explanation of the relevance of each cited reference conforming to the requirements of 37 C.F.R. §1.98(a)(3).

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing Form PTO-1449 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of

examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Adda G. Gogoris', is written over a horizontal line.

Adda G. Gogoris  
Reg. No. 29,714  
Attorney For Applicant(s)

DARBY & DARBY P.C.  
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New York, NY 10022  
(212) 527-7700

**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 6485/16895 SERIAL NO: N/A  
APPLICANT: Giancarlo SANTUS et al. FILING DATE: concurrently herewith  
CONFIRMATION NO:

**U.S. PATENT DOCUMENTS**

| <u>*EXAMINER<br/>INITIALS</u> | <u>DOCUMENT<br/>NUMBER</u> | <u>DATE</u> | <u>NAME</u>  | <u>CLASS</u> | <u>SUBCLASS</u> | <u>FILING DATE</u> |
|-------------------------------|----------------------------|-------------|--------------|--------------|-----------------|--------------------|
|                               | 1. 4,089,569               | May, 1978   | Muchowski    | 514          | 416             | Feb., 1977         |
|                               | 2. 4,478,822               | Oct., 1984  | Haslam       | 424          | 78              | May, 1983          |
|                               | 3. 4,778,810               | Oct., 1988  | Wenig et al. | 514          | 263             | Jan., 1987         |
|                               | 4. 4,885,287               | Dec., 1989  | Hussain      | 514          | 159             | August, 1988       |
|                               | 5. 4,973,596               | Nov., 1990  | Cohen        | 514          | 354             | May, 1988          |
|                               | 6. 6,090,368               | July, 2000  | Zia et al.   | 424          | 45              | March, 1998        |

**FOREIGN PATENT DOCUMENTS**

| <u>*EXAMINER<br/>INITIALS</u> | <u>DOCUMENT<br/>NUMBER</u> | <u>DATE</u> | <u>COUNTRY</u> | <u>CLASS</u> | <u>SUBCLASS</u> | <u>TRANSLATION</u><br><u>YES</u> <u>NO</u> |
|-------------------------------|----------------------------|-------------|----------------|--------------|-----------------|--|
|                               | 7. WO 88/04929             | 7/14/88     | PCT            | A61K31       | 52 & 62         | English                                    |
|                               | 8. WO 90/07333             | 7/12/90     | PCT            | A61K31       | 445             | English                                    |

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CONFIRMATION NO:\*EXAMINER  
INITIALS**OTHER REFERENCES****(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**\*EXAMINER  
INITIALS

9. Mroszczak, E. J., et al., Ketorolac Tromethamine Absorption, Distribution, Metabolism, Excretion, and Pharmacokinetics in Animals and Humans, *Drug Metab. Dispos.*, 15 (5):618-626, 1987
10. Chien, Y.W. and Chang, S.F., Historical Development of Transnasal Systemic Medications; In: *Transnasal Systemic Medications*, edited by Y.W. Chien, Elsevier Science Publishers B.V., Amsterdam, 1985
11. Buckley, M.M.T., *Drugs* 39:86-109, 1990.
12. Yu, D., *Pharmaceutical Research* 5 :457-462, 1988.
13. Rooks, W.H. *Drugs Exptl. Clin. Res.* 11:479-492, 1985.
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16. Morimoto, K., *J. Pharm. Pharmacol.* 37:134-136, 1985.
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18. Pennington, A.K., International Journal of Pharmaceutics 43:221-224, 1988.
19. DePonti, R., Drug Development and Industrial Pharmacy 17:1419-1436, 1991.

EXAMINER: \_\_\_\_\_

DATE CONSIDERED: \_\_\_\_\_

\*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

JCS73 U.S. PTO  
09/903665  
07/13/01